



Concerta (methylphenidate, controlled release)

Generic name: Methylphenidate, controlled-release

Available strengths: 18 mg, 27 mg, 36 mg, 54 mg tablets

Available in generic: No, only immediate-release methylphenidate

Drug class: Stimulant

General Information

Concerta (methylphenidate, controlled release) is a psychostimulant, or better known as a stimulant. Concerta is used primarily in treating **attention-deficit/hyperactivity disorder** (ADHD) and **narcolepsy**, a condition characterized by daytime somnolence in which the patient periodically falls into a deep sleep during the day. Narcolepsy is a disorder of the sleep-wake control mechanisms within the brain that interferes with both daytime wakefulness and nighttime sleep.

The use of a medication for its approved indication is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of these medications for these unapproved indications. Concerta is often used to augment antidepressants in treating refractory depression. For patients with chronic treatment-resistant depression, for example, Concerta in combination with antidepressants can provide symptomatic relief and improvement beyond that experienced with antidepressants alone.

In numerous clinical studies and decades of clinical experience, Concerta has clearly demonstrated improvement in outcome for children with ADHD. Concerta increases the child’s ability to concentrate, extends attention span, and decreases hyperactivity. Adults with ADHD also benefit from therapy with Concerta. Concerta helps them concentrate and remain focused on their tasks, increases their attention span, and decreases impulsivity and hyperactivity.

Concerta tablets deliver methylphenidate in two phases using advanced technology. In the first phase, the stimulant is released within 1–2 hours from the outer coat of the tablet to provide rapid onset of action; in the second phase, the remainder is released at a controlled rate over 10–12 hours. The tablet is composed of a core, containing the stimulant, which is surrounded by a membrane that controls the time-released system. The core is enveloped by an outer coat containing a layer of methylphenidate. When the Concerta tablet is ingested, the outer coat dissolves within 1–2 hours, providing the initial dose of methylphenidate. During gastrointestinal passage of the tablet, the remainder of the stimulant is gradually released from the core of the tablet. The empty tablet shell is expelled in the stool.

Concerta tablets should be swallowed whole and never chewed or crushed. Chewing or crushing the tablets destroys the controlled-release system. Concerta should be taken early in the morning with or without food. If taken late in the day, the stimulant effect can be prolonged into the night and interfere with sleep.

Dosing Information

For adults, the usual starting dosage for immediate-release methylphenidate is 5 mg twice a day, and the dosage is adjusted based on the individual's response. The average dosage is 20–30 mg/day, administered two or three times daily. The maximum dosage should not exceed 60 mg/day. Concerta may be used in place of regular methylphenidate, Ritalin-SR, or Metadate-ER by replacing the total daily dosage with the nearest equivalent dose of Concerta. For example, 5 mg of methylphenidate twice daily (10 mg/day) or three times a day (15 mg/day) could be replaced with 18 mg of Concerta once a day. In addition, 20 mg/day of Ritalin-SR or Metadate-ER could also be converted to 18 mg of Concerta once a day.

Individuals new to methylphenidate may initially take 18 mg of Concerta once a day in the morning. The dosage may be adjusted at weekly intervals to the next higher strength, depending on response, up to a maximum dosage of 54 mg/day.

Common Side Effects

The common side effects associated with taking Concerta are rapid heart rate, palpitations, nervousness, restlessness, insomnia, dry mouth, constipation, nausea, diarrhea, loss of appetite, weight loss, and elevation of blood pressure.

Adverse Reactions and Precautions

Concerta has a high potential for abuse. Individuals with a history of alcohol and substance abuse may be at risk for abusing stimulants. Individuals who abuse Concerta develop tolerance and psychological dependence that may result in addiction. With long-term abuse of Concerta and the resulting sleepless nights, the individual may develop psychotic symptoms.

Concerta may increase blood pressure. Individuals with a history of high blood pressure or heart disease should be cautious about taking Concerta because it can exacerbate these conditions. Uncontrolled high blood pressure can have serious consequences, including stroke and heart attacks. Patients taking Concerta should routinely check their blood pressure.

Individuals with a history of seizure disorder should be cautious while taking Concerta, because it can lower the seizure threshold.

In children and adolescents who are still in their growth period, Concerta can suppress linear growth. Physicians commonly interrupt treatment, if possible, on weekends and holidays, when children are not in school, for growth catch-up. Children and adolescents taking Concerta require close monitoring for growth suppression and periodic measuring of their height. This effect is not a concern in the adult population.

Concerta may make tics worse in individuals with a tic disorder (i.e., twitching of a muscle group, especially in the face).

Concerta should be avoided, or used with caution, by patients with a diagnosis of schizophrenia or bipolar disorder. Stimulants are frequently abused in this population, and high doses of Concerta may trigger psychosis and mania.

Possible Drug Interactions

Concerta should not be taken in combination with a group of antidepressants known as **monoamine oxidase inhibitors**. The combination may precipitate increases in blood pressure. This and other significant drug interactions reported with Concerta are summarized in the table below.

Ismelin (guanethidine)	The antihypertensive effects of Ismelin (i.e., lowering of blood pressure) may be decreased when combined with Concerta.
Monoamine oxidase inhibitors (MAOIs)	MAOI antidepressants (e.g., Parnate) should not be taken with Concerta; the combination may precipitate dangerous elevation of blood pressure.
Selective serotonin reuptake inhibitors (SSRIs)	Concerta and other stimulants may elevate the blood levels of SSRI antidepressants (e.g., Paxil, Prozac) and enhance their effects.
Weight-loss medications	Weight-loss medications, prescription and non-prescription, should not be taken with stimulants. Excess stimulation may cause agitation, irritability, insomnia, and other adverse reactions.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Concerta has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. Women who are pregnant or may become pregnant should discuss this with their physician.

Nursing mothers should not take any stimulant, because small amounts will pass into breast milk and be ingested by the baby. If stopping the stimulant is not an alternative, breastfeeding should not be started or should be discontinued.

Overdose

The severity of acute Concerta overdose depends on the amount ingested. The individual may experience a progression of the following symptoms from an acute overdose: restlessness, agitation, irritability, insomnia, hyperactivity, confusion, elevated blood pressure, rapid heart rate, delirium, hallucinations, irregular heart beat, convulsions, coma, circulatory collapse, and death.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

